active principle, for example, as an oil and water emulsion, lotion, gel or cream. The excipient facilitates topical application of the cosmetic or dermatological product.

A cosmetic or dermatological product according to the claimed subject matter is made essentially of components, which cannot be classified as or categorized between an active ingredient and a vehicle. As disclosed in col. 2, lines 56-63, each disclosed component or any combination thereof behaves as an active ingredient, e.g., for treating the skin, <u>and</u> as a vehicle for creating a suitable and stable topical form for the application of the product.

Claim 1 recites a cosmetic or dermo-therapeutic composition for a direct application onto surface parts of the human body, in a form adapted for said direct application, said composition comprising: a biodermal fraction representing 98-100% by weight of the composition, comprising at least two different biodermal constituents, each being cytocompatible with skin; and a non-biodermal fraction representing 0-2% by weight of the composition, comprising at least one non-biodermal constituent that is compatible with skin, said composition having no excipient or vehicle adapted to said form of the composition, wherein, if water is one of the constituents, it is part of the biodermal fraction and represents a minor part by weight of said composition.

Accordingly, the claimed subject matter is concerned with a <u>final</u> product, i.e., a product that is ready to be used. A prior art reference disclosing an intermediate active ingredient within the above indicated weight range does not anticipate the claimed subject matter if the prior art discloses a <u>final</u> product that has less than 98% weight percent active ingredient.

The Office Action asserts that the Abstract of Bernstein discloses that Bernstein's lipid concentrate can be applied directly and that a vehicle is not required. This assertion is incorrect. Specifically, the Abstract in Bernstein discloses that "the concentrate may be applied topically as prepared." All the formulations disclosed in Bernstein, i.e., the

concentrates as prepared, comprise lipid concentrates in a weight range between 5 and 10%.

Bernstein further discloses that "the resulting lipid concentrate formulation may be then added to cream, ointment, gel or lotion vehicles," thereby further reducing the weight percentage of the active ingredient. Thus, Bernstein fails to disclose the combination of all of the features positively recited in independent claim 1 despite the assertions to the contrary in the Office Action.

Claims 2, 3, 5-8, 12, 16, 18-20, 23 and 29 depend, directly or indirectly, from claim 1, thereby inheriting all of the features of claim 1. As such, Bernstein cannot reasonably be considered to teach the combination of features recited in the enumerated claims. The dependent claims are in condition for allowance for at least the same reasons as claim 1, as well as for the additional features recited in these claims. Accordingly, reconsideration and withdrawal of the rejection of the enumerated claims as being anticipated by Bernstein are respectfully requested.

Claims 1, 9-11 and 13 are rejected under 35 U.S.C. §103(a) over Bernstein. This rejection is respectfully traversed.

The Office Action alleges that Bernstein teaches using water in the amount of 50% and that a skilled artisan would be motivated to optimize the specific amount. This assertion is incorrect for at least the following reasons.

Claim 1 recites that "if water is one of the constituents, it is part of the biodermal fraction and represents a minor part by weight of said composition." Thus, if water is present, it is part of the fraction that exerts a beneficial action or result on an exterior portion of the human body. Bernstein discloses therapeutic formulations of lipid concentrates made without water. Bernstein's active ingredient is then mixed with the water containing vehicle.

Further, even if Bernstein were to disclose water as one of the constituents of the active principle, the Office Action fails to demonstrate that a skilled artisan would be

motivated to vary the therapeutic formulations of Bernstein. The Office Action, in its conclusory statement that such would have been obvious not only must ignore the positive discussion in the disclosure, but must also apply improper hindsight reasoning based on Applicant's disclosure in order to assert that subject feature would have been obvious, and must also ignore Federal Circuit precedent that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, Appeal No. 04-1616, March 22, 2006 (Fed. Cir). Specifically, only Formula 3 in Bernstein discloses 50 % water by weight. All the other Formulas disclose higher water contents. Bernstein, in the second table in col. 4, teaches that Formula 3 is slightly less efficient than Formula 1 and Formula 2, both having higher water content, in preventing evaporative water loss. Thus, a skilled artisan would not be motivated to further reduce the water content of the vehicle in Bernstein. If anything, a skilled artisan would try to optimize the water content around 51%, which is the content of the most efficient formulation for preventing water loss. More likely, a skilled artisan would conclude that the water content is not a result-effective variable, because the water content of Formulas 1-3 in Bernstein does not change the prevention of water loss by more than 0.2 percentage points.

For the reasons set forth above, Bernstein fails to suggest all the features of independent claim 1. Claims 9-11 and 13 depend, directly or indirectly, from claim 1. Claims 9-11 and 13 are in condition for allowance for at least the same reasons as claim 1, as well as for the additional features recited therein. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1, 9-11, 16, 21 and 22 are rejected under 35 U.S.C. §103(a) over Bernstein in view of Yu. This rejection is respectfully traversed.

The Office Action relies on Yu for allegedly disclosing the features of claims 9-11, 21 and 22. The Office Action acknowledges that Bernstein and Yu do not disclose the weight amounts of the composition recited in claim 1. However, the Office Action further alleges that the "amount of a specific ingredient is clearly a result effective parameter," without giving any explanation why this would be the case. As understood by Applicant, the Office Action suggests that a skilled artisan would attempt to "optimize" the weight percentage of the vehicles disclosed in Bernstein or Yu to 0%.

For the reasons set forth above, Bernstein cannot reasonably be considered to teach, or to have suggested, all of the features of claim 1. It is unclear why Yu would cure the deficiency of Bernstein. The Office Action, in its conclusory statement that "it would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired result," fails to give any specifics why Yu would provide motivation to change the formulations of Bernstein. The Office Action failed to meet the burden of properly expressing this rejection.

It is noted that Yu discloses a "pharmaceutically acceptable vehicle," in col. 12, line
46. Thus, Yu fails to teach or suggest a "composition having no excipient or vehicle adapted to said form of the composition," as positively recited in claim 1.

For the reasons set forth above, Bernstein and/or Yu fail to teach or suggest all of the features of independent claim 1. Claims 9-11, 16, 21 and 22 depend, directly or indirectly, from claim 1. The dependent claims are in condition for allowance for at least the same reasons as claim 1, as well as for additional features they recite. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted

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Daniel A. Tanner, III Registration No. 54,734

WPB:DAT:GMH/jth

Attachment:

Petition for Extension of Time

Date: February 7, 2007

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